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MAY 12 2006
PATENT & TRADEMARK OFFICE

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	)	
Richard G. Olsen, *et al.*	)	
Serial No. 08/943,993	)	
Filed: October 3, 1997	)	Examiner Ronald B. Schwadron, Ph.D.
For: EXPANSION OF CYTOKINE-PRODUCING	)	Group Art Unit 1816
CELLS FROM LYMPH NODES INFECTED	)	
WITH HUMAN IMMUNODEFICIENCY	)	
VIRUS-1 FOR USE IN CELLULAR	)	
IMMUNOTHERAPY	)	

ASSISTANT COMMISSIONER OF PATENTS
WASHINGTON, D.C. 20231

AFFIDAVIT UNDER RULE 132

Sir:

Pierre L. Triozzi, being duly sworn according to law, does depose and say that:

1. He has an A.B. degree from Cornell University (1977); and an M.D. degree from The Ohio State University (1980).
2. He was an intern at the Department of Medicine, Duke University Medical Center (1980-1981); a resident at the Department of Medicine, Duke University Medical Center (1981-1983); and a fellow at the Division of Hematology and Oncology, Duke University Medical Center (1983-1986).
3. He was a Clinical Assistant Professor (1986-1988) and an Assistant Professor (1988-1993), and now is Associate Professor, Division of Hematology and Oncology, Department of Internal Medicine, The Ohio State University; and is Director, Ambulatory Oncology Unit (1988-present), Director, Biological Responsive Modifier Program, and Co-Director, Immunology Program (1993-Present) at The Ohio State University Comprehensive Cancer Center.
4. His board certifications, professional memberships, honors/awards, editorial boards, grant review, grants/contracts, clinical service, presentations, patents, publications, book chapters, invited reviews and editorials, audiovisual, and abstracts are set forth in his Affidavit Under Rule 132 dated September 16, 1996, which is expressly incorporated herein by reference.
5. He has read the above-identified application for letters patent and the Office action mailed April 3, 1997.
6. He supervised and directed additional testing comparing the expansion of lymph node lymphocytes and peripheral blood lymphocytes from the same patient (n = 2 lymph nodes; Patients A and B).

7. The results of such testing is set forth in the attached graph where the cell expansion of CD4 and CD8 cells is compared for peripheral blood and for lymph nodes.
8. These results clearly show that the cell expansion for peripheral blood lymphocytes was far less than that for lymph node lymphocytes.
9. He also supervised and directed additional testing comparing the production of MIP-1α and of RANTES from cells expanded from lymph node lymphocytes and from peripheral blood lymphocytes from the same patients.
10. The results of this testing also is set forth in an attached bar graph.
11. These results also show that significantly more chemokines are produced by expanded lymph node lymphocytes than are produced by peripheral blood.
12. It is his considered opinion based on his expertise and experience, and based on his supervision of the pilot study under an IND granted by the FDA based on the above-identified invention, that use of lymph node lymphocytes would result in a much more effective treatment of HIV patients for both reduction of viral load and for restoration of immune function (immunorestorative effect) compared to peripheral blood lymphocytes.
13. It also is his considered opinion that it would not have been not obvious to use lymph nodes as the source of lymphocytes for use in preparing an adoptive cellular therapy therapeutic agent based on literature references that have used peripheral blood lymphocytes for preparing such therapeutic agents (which therapeutic agents have not been reported as being effective in treating HIV patients), and that the test results reported herein sustain such opinion.
14. If anything, it may be considered counter-intuitive to use a major reservoir of HIV, *i.e.*, lymph nodes, and the central target of HIV infection, *i.e.*, activated CD4+ cells, in the adoptive cellular therapy of HIV infection.
15. He is unaware of any prior reference that utilizes excised lymph nodes that are subjected to mitogenic stimulation for preparation of a therapeutic agent for administration to HIV-positive patients, nor does he believe that it would have been obvious to the skilled artisan to use such excised lymph nodes based on similar work using peripheral blood as the source for lymphocytes; therefore, he believes that the invention disclosed in the above-identified application is patentable.

FURTHER AFFIANT SAYETH NAUGHT.

Date: 12-18-97

Pierre L. Triozzi, M.D.

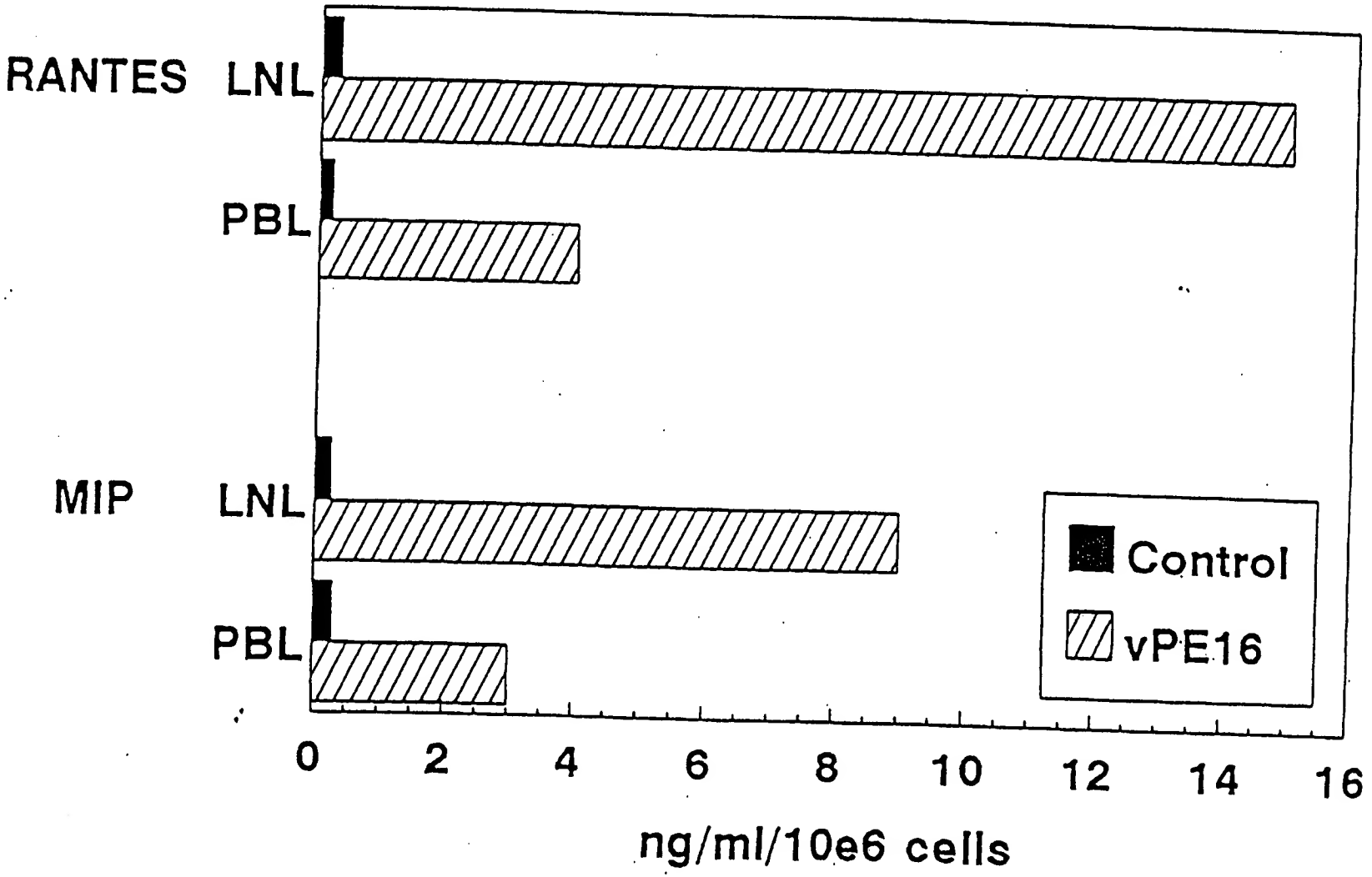
State of Ohio)
) ss
County of Franklin)

Sworn to and subscribed before me this 18th day of December, 1997.

Notary Public

JERRY K. MUELLER, JR., Attorney-at-Law
Notary Public, State of Ohio
My Commission Has No Expiration Date
Section 147.03 R. C.

CHEMOKINE PRODUCTION
LYMPH NODE (LNL) V. PERIPHERAL BLOOD (PBL)



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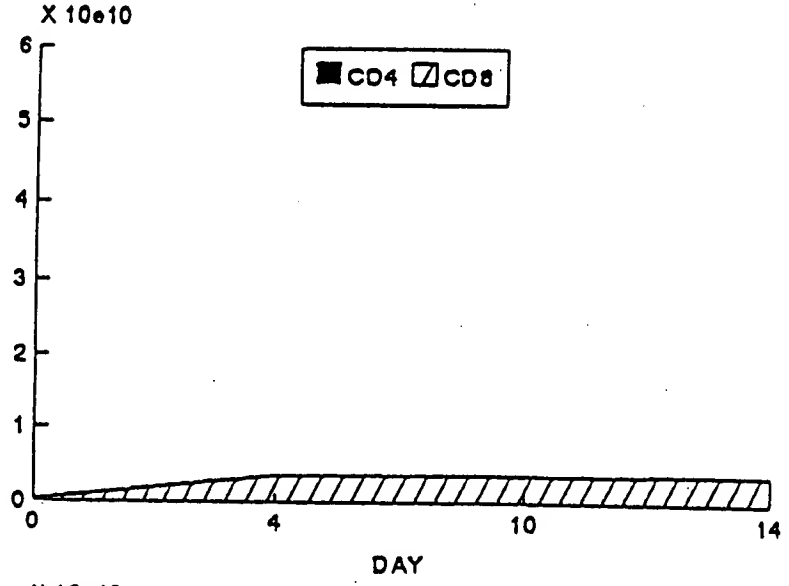
10-day OKT3/IL-2 expanded cells

EXPANSION

PERIPHERAL BLOOD

A



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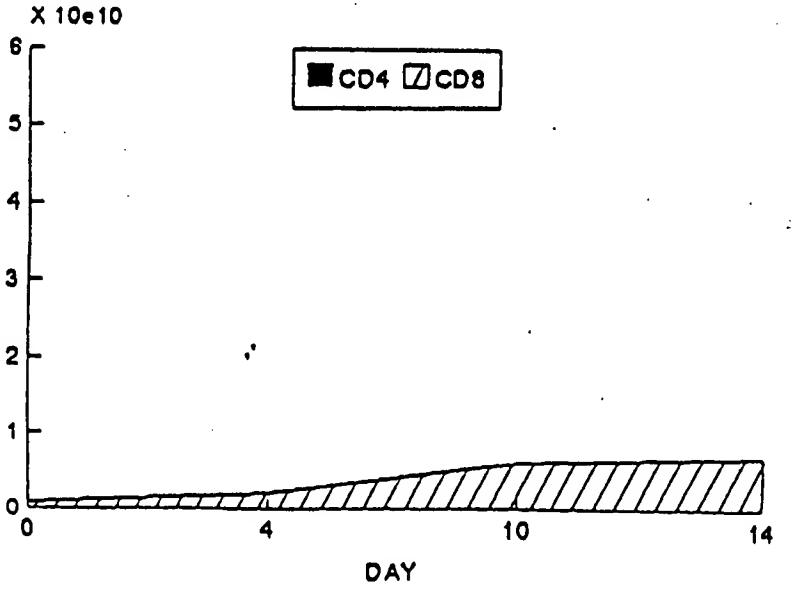

LYMPH NODE